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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-----------------|----------------------|-------------------------|------------------|
| 09.591,737 | 06/12/2000 | David T. Curiel | D6167CIP | 3628 |
| 27851 7 | 7590 07.01.2003 | | | |
| BENJAMIN A. ADLER | | | EXAMINER | |
| 8011 CANDLE LANE HOUSTON, TX 77071 | | | LI, QI | AN J |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | 17 |
| | | | DATE MAILED: 07/01/2003 | • |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Applic | cation No. | Applicant(s) | | | |
|---|---|--|---|---|--|--|--|
| | | 09/59 | 1,737 | CURIEL ET AL. | | | |
| Office Action Summary | | | iner | Art Unit | | | |
| | | Q. Jar | | 1632 | | | |
| Period fo | The MAILING DATE of this commu or Reply | nication appears on | the cover sheet | with the correspondence address | | | |
| THE N - Exter after - If the - If NO - Failur - Any ri | ORTENED STATUTORY PERIOD IN MAILING DATE OF THIS COMMUN ISSUE of time may be available under the provision SIX (6) MONTHS from the mailing date of this comperiod for reply specified above is less than thirty (period for reply is specified above, the maximum size to reply within the set or extended period for repleply received by the Office later than three months dipatent term adjustment. See 37 CFR 1 704(b) | IICATION. s of 37 CFR 1 136(a) In n munication 30) days, a reply within the statutory period will apply ai y will, by statute, cause the | to event, however, may estatutory minimum of t and will expire SIX (6) M e application to become | a reply be timely filed hirty (30) days will be considered timely DNTHS from the mailing date of this communication ABANDONED (35 U S C § 133) | | | |
| 1)[| Responsive to communication(s) f | iled on <u>07 A<i>pril</i> 200</u> | <u>03</u> . | | | | |
| 2a) | This action is FINAL . | 2b)⊠ This action | n is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | | |
| · | | 4-56 is/are pending | g in the application | on. | | | |
| 4)[·] Claim(s) <u>1,3-17,19-21,23-31 and</u> 34-56 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) 31,34-40,42,43,45-53 and 55 is/are allowed. | | | | | | | |
| 6) Claim(s) <u>1,3-17,19-21 and 23-30</u> is/are rejected. | | | | | | | |
| 7) Claim(s) 41,44,54 and 56 is/are objected to. | | | | | | | |
| | • | | on requirement. | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. Application Papers | | | | | | | |
| 9) 🗌 🗆 | The specification is objected to by th | ie Examiner. | | | | | |
| 10) The drawing(s) filed on 12 June 2000 is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.O. \$5,100 and in 101 | | | | | | | |
| | turis# spiris statement(s) (PTO-1449) i | | b) Other | en de la companya de | | | |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2003 has been entered.

Claims 11, 12, 14, 15, 17, 19, 21, 23, 31, 40, 41, 43, 44, and 53-56 have been amended. Claim 33 has been canceled. Claims 1, 3-17, 19-21, 23-31, and 34-56 are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in paper #15 would be addressed to the extend that they apply to the current rejection.

Priority

This application is a continuation-in-part of US application 09/407, 511, now U.S. patent 6,284,742, which claim priority to U.S. provisional application 60/102,257, filed 9/29/1998. Applicants should amend the cross-reference section of the specification to update the status of the parent application.

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Claims 31, and 34-56 are drawn to a recombinant adenoviral vector comprising a chimeric fiber protein comprising CD40 ligand and bacteriophage T4 fibritin, and methods of using such. The subject matter has not been disclosed in the parent application, therefore, the priority date for these claims is established as the filing date of instant application, i.e. 6/12/2000. Applicants are invited to specifically point out where the support for these claims could be found in the parent application.

Claim Objections

Claims 11, 12, 14, 15, 19, 23, 41, 44, 54, 56 are objected to because of the inconsistent claim recitations, such as "said CD40+ immune cells", "said immune cells", "said dendritic cells", or "said cells". Although it is understandable that the various recitations refer to CD40+ immune cells or dendritic cells of the previous claim, it is confusing that such cells have been referred to with different terms in the claims, such as "said immune cells" (claims 11, 14), or "said cells" (claims 12, 15, 19, 23, 41, 44, 54, 56). Applicants are suggested to amend the claims for clarity and consistency.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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Claim 4 recites the limitation "said antibody directed against CD40 antigen".

There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 416 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-10, 25, 26 <u>stand</u> rejected and claims 11-17, 19-21, 23, 24, 27-30 are <u>newly</u> rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,284,742, for reasons of record and following.

In paper No. 15, Applicants acknowledged the merit of the rejection of claims 1, 3-10, 25, 26 without amending claim or filing a terminal disclaimer, thus, the rejection stands.

Claims 11-17, 19-21, 23, 24, 27-30 are newly rejected as being unpatentable over claims 1-6 of U.S. Patent No. 6,284,742. Claims 1-6 of the cited patent are drawn

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17, 19-21, 23, 24, 27-30 are drawn to methods of using such gene delivery system for delivery a gene of interest to APCs (CD40+ immune cells), which methods are fully disclosed in the specification of the cited patent (e.g. Examples 11-15).

Accordingly, the instant claims and claims of cited patent are co-extensive.

Conclusion

Claims 31, 34-40, 42, 43, 45-53, and 55 are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li Examiner
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QJL June 30, 2003